



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

April 8, 2004

Mr. Deepak Naik
First Priority, Inc.
1585 Todd Farm Drive
Elgin, Illinois 60123-1146

FILE COPY

Dear Mr. Naik:

Your petition requesting the Food and Drug Administration to seek permission to file an ANADA for a generic equivalent of the innovator product, Garacin (gentamicin sulfate) Pig Pump Oral Solution, which differs in the concentration of the active ingredient from innovator product, was received by this office on 04/08/2004. It was assigned docket number 2004P-0167/ CP 1 and it was filed on 04/08/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2004P 0167

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